DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DATE: March 27, 2006

FROM: Michael Bernstein (HFD-7)

SUBJECT: Docket No. 2005P-0400

TO: Dockets Management Branch (HFA-305)

Please file this memo in the Docket referenced above.

The above Citizen Petition was received by FDA on September 27, 2005. The Petition requested that FDA provide the petitioner, Donna Ricks, with access to the drug Palladone (hydromorphone hydrochloride) for relief of severe pain due to terminal cancer. Palladone's sponsor, Purdue Pharma, suspended marketing of Palladone in July 2005.

Such requests are generally treated as requests for a single patient Investigational New Drug Application (IND). Because single patient INDs for drugs are generally established by the appropriate FDA reviewing division, the Office of Regulatory Policy forwarded the Petition to the Division of Analgesics, Anesthetics, and Rheumatology Products (DAARP). DAARP immediately contacted Ms. Ricks and her doctor to request additional information necessary to establish a single patient IND. Upon further inquiry, it was recently determined that the petitioner died on January 7, 2006. Accordingly, the Petition is now moot, and the docket can be closed.